

REMARKS

The requirement for restriction was directed to claims 1-39. Claims 1, 4-7, 11-15, and 38-39 are canceled herein. New claims 40-51 are presented herein for the Examiner's consideration. Entry of these claims is respectfully requested. Upon entry of these amendments, original claims 2, 8, 9, 25, 26, and 28; previously amended claims 3, 10, 16-24, 27, and 29-33; previously added claims 34-37; and new claims 40-51 are pending in the present application.

Support for the new claims can be found in the original claims and throughout the specification. Specifically, support for new claims 40-49 can be found in original claims 1, 4-7, and 11-15, respectively. Support for new claims 50-51 is found in previously added claims 38 and 39. No issue of new matter is introduced by these claims.

By this Office Action, the Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

- Group I. Claims 1-7, 11-21, 38 and 39 are drawn a recombinant protein that exhibits significant homology with the tick-derived protease inhibitor protein sequence set forth in SEQ ID NO:2, a pharmaceutical composition comprising said protein, a vaccine comprising said protein and a process for the formulation of a pharmaceutical composition comprising said protein.
- Group II. Claims 8-13, 16-21 are drawn to a recombinant protein derived from a blood-feeding arthropod ectoparasite that inhibits tryptase and a pharmaceutical composition comprising said protein, a vaccine comprising said protein, and a process for the formulation of a pharmaceutical composition comprising said protein.
- Group III. Claims 22, 31, 32 and 34 are drawn to a method for preventing or treating a disease in a subject, comprising administering to said subject a pharmaceutical composition, comprising a recombinant protein that exhibits significant sequence homology with the tick-derived protease inhibitor protein sequence set forth in SEQ ID NO:2.
- Group IV. Claims 22 and 34 are drawn to a method for the prevention or treatment of a disease in a subject, comprising administering to said subject a

pharmaceutical composition, comprising a recombinant protein derived from a blood-feeding arthropod ectoparasite that inhibits tryptase.

- Group V. Claims 23-27, 29 and 35 are drawn to a nucleic acid molecule encoding a recombinant protein that exhibits significant homology with the tick-derived protease inhibitor protein sequence set forth in SEQ ID NO:2, a vector and host cells and a method of producing said protein.
- Group VI. Claim 28 is drawn to a transgenic animal that has been transformed by a nucleic acid molecule encoding a recombinant protein that exhibits significant homology with the tick-derived protease of SEQ ID NO:2.
- Group VII. Claim 30 is drawn to method for the detection or quantification of tryptase.
- Group VIII. Claim 33 is drawn to a tryptase inhibitor.
- Group IX. Claims 36 and 37 are drawn to a method for the depletion or removal of tryptase from a food product or a cell culture comprising contacting the food product or cell culture with a recombinant protein that exhibits significant homology with tick-derived protease inhibitor protein sequence set forth in SEQ ID NO:2.

Responsive to the Requirement for restriction, Applicants elect to prosecute the invention of Group II, with traverse, Claims 8-13 and 16-21, which are drawn to a recombinant protein derived from a blood-feeding arthropod ectoparasite that inhibits tryptase and a pharmaceutical composition comprising said protein, a vaccine comprising said protein, and a process for the formulation of a pharmaceutical composition comprising said protein.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of new claims 40-51 presented herein. In that the new claims are directly or indirectly dependent from claims designated in Group II, applicants assert that the claims of Group II and new claims 40-51 are fundamentally related to each other.

Moreover, under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if

"there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the search for any of the claims of Group II would require an additional search of the **identical** classes wherein new claims 40-51 are classified, thus resulting in a duplicate search for the same material. Thus, Applicants submit that the Search and Examination of the entire Application, or, at least, of Group II with new claims 40-51 can be made without serious burden, and therefore the Examiner should examine all of the claims of the Application on the merits.

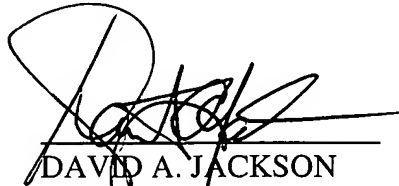
No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

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In view of the above, modification of the Requirement for the Restriction is requested,
and an early action on the merits of the Claims is courteously solicited.

Respectfully submitted,



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